

MAY 23 2012

K120487

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k)
Vantage Titan 3T, v2.0, MRT-3010/A5

510(k) SUMMARY AND EFFECTIVENESS

1. DEVICE NAME:

Generic Name: Magnetic Resonance Diagnostic Device
Model Name: MRT-3010/A5
Trade/ Proprietary Name: Vantage Titan 3T

2. ESTABLISHMENT REGISTRATION: 2020563

3. U.S AGENT INFORMATION:

U.S. Agent Name: Paul Biggins
(714) 730-5000

Establishment Name and Address: Toshiba America Medical Systems, Inc.
2441 Michelle Drive
Tustin, Ca. 92780

4. MANUFACTURING SITE: Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550
Japan

5. DATE OF SUBMISSION: February 16, 2012

6. DEVICE DESCRIPTION:

The Vantage Titan 3T (Model MRT-3010/A5) is a 3 Tesla Magnetic Resonance Imaging (MRI) System(K113093). Four software packages (Positioning Assist for Cardiac, Diffusion Tensor Tractography (DTT) , Cardiac Function Analysis, and Image filter EM AIDR are added to Vantage Titan 3T.

6. SUMMARY OF MAJOR HARDWARE CHANGES

Not applicable.

7. SUMMARY OF MAJOR SOFTWARE CHANGES

Existing software (V1.35) packages are grouped by functions of software and pulse sequences. New software (V2.0) packages are added four application software as follows:

a) Positioning Assist for Cardiac

This function of software assists the operator to position for scanning for Cardiac imaging for easy operation. The operator shall confirm the patient position before

starting the cardiac scanning and the operator can re-adjust the scanning position if needed.

b) Diffusion Tensor Tractography (DTT)

- i. DTT represents direction of the central nerves by using anisotropy of diffusion coefficients calculated from the DTI map.
- ii. The central nerves are represented as bundle fibers in 3D volume.
- iii. DTT can visualize the fusion of SVR with cut-off plan. DTI maps and bundle of fibers in 3D view.
 - a. SVR- is reconstructed Surface Volume Rendering image from anatomical images.
- iv. DTT can also visualize the fusion of cross sections, DTI maps and bundle of fibers

c) Cardiac Function Analysis

This function of software makes cardiac cine image and visual evaluation of wall motion abnormality. This function shows the graphs and tables of the result of cardiac function analysis like Bull's eye map of wall thickening.

d) Image filter EM AIDR

This is an image filter which can reduce the ringing artifact especially in low resolution images.

8. SAFETY PARAMETERS

Item	Vantage Titan 3T (subject device)	Vantage Titan 3T K113093 (Predicate Device)	Notes
Static field strength	3T	3T	Same
Operational Modes	1 st Operating Mode	1 st Operating Mode	Same
i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1 st level operating mode	Allows screen access to 1 st level operating mode	Same
Maximum SAR	4W/kg for whole body (1 st operating mode specified in IEC 60601-2-33(2002))	4W/kg for whole body (1 st operating mode specified in IEC 60601-2-33(2002))	Same
Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	<1st operating mode specified in IEC 60601-2-33 (2002)	Same
Potential emergency condition and means provided for shutdown	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same

10. IMAGING PERFORMANCE PARAMETERS

No change from the previous predicate submission (K113093).

11. INTENDED USE

Vantage Titan 3T systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.

MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical Shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

No changes to the previously cleared indication (K113093).

12. DESIGN CHANGE

Following software package addition to Vantage Titan 3T (K113093).

- a) Positioning Assist for Cardiac
- b) Diffusion Tensor Tractography (DTT)
- c) Cardiac Function Analysis
- d) Image filter EM AIDR (Development name is "EMTONE")

13. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for software of changing packages is included in this submission. The test methods used are the same as those submitted in the previously cleared submissions (K113093). A declaration of conformity with design controls is included in this submission.

14. TRUTHFUL AND ACCURACY CERTIFICATION

A certification of the truthfulness and accuracy of the Vantage Titan 3T described in this submission is provided in this submission.

15. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan 3T (model MRT-3010/A5) Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate devices referenced in this submission.

Testing was done in accordance with applicable recognized consensus standards as listed below.

List of Applicable Standards

- | | |
|--|-------------------------|
| • IEC60601-1:1988, Amd.1:1991, Amd.2:1995 | • IEC62304:2006 |
| • IEC60601-1-1:2000 | • IEC62366:2007 |
| • IEC60601-1-2:2001, Amd.1:2004 | • NEMA MS-1:2008 |
| • IEC60601-1-4:1996, Amd.1:1999 | • NEMA MS-2:2003 |
| • IEC60601-1-6:2006 | • NEMA MS-3:2008 |
| • IEC60601-1-8:2003, Amd.1:2006 | • NEMA MS-4:2006 |
| • IEC60601-2-33:2002, Amd.1:2005, Amd.2:2007 | • NEMA MS-5:2003 |
| • IEC60825-1: 2007 | • NEMA PS 3.1-18 (2008) |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Regulatory Affairs Director
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

MAY 23 2012

Re: K120487

Trade/Device Name: MRT-3010/A5, Vantage Titan 3T, v2.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 12, 2012
Received: April 13, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

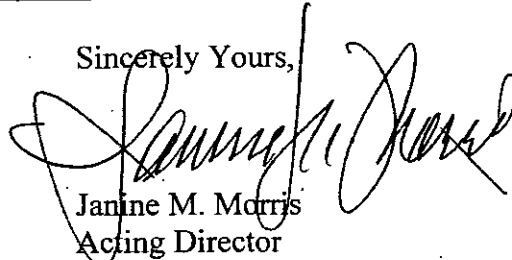
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120487

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k)
Vantage Titan 3T, v2.0, MRT-3010/A5

Indications for Use

510(k) Number (if known): _____

Device Name: MRT-3010/A5, Vantage Titan 3T, v2.0

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number K120487

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Indication for Use
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